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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,422	12/27/2005	Tina Rademacher	RO4126US (#90568)	3869

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D. PETER HOCHBERG CO. L.P.A.
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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
09/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,422	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 20-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1 – 15 and 20 – 29 in the reply filed on July 7, 2008 is acknowledged. Applicant traverse on the basis that the subject matter of the independent claims are interrelated with each other in that they refer to the same kind of product and that the cited prior art of Gibson et al. fails to disclose directly and unequivocally a dried, film-shaped administration form.

These arguments are not found to be persuasive. The interrelated nature of the claims to the same product establishes that a common technical feature is present. In order for the common technical feature to be a special technical feature and establish unity of invention requires that the common technical feature be a contribution over the prior art. While Gibson et al. may not unequivocally show all the claimed elements of a dried, film-shaped administration forms with the same intended use are taught by Kigasawa et al. (US 4,572,832). Therefore the restriction requirement between the groups is maintained.

Information Disclosure Statement

2. No copies of the documents cited on PTO-1449, submitted December 27, 2005 have been submitted although a copy of the international search report has been

supplied. The documents have been considered to the extent that they are discussed in the ISR and IPER.

Claim Rejections - 35 USC § 112 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Markush group of items for the matrix-forming polymer contains the items polyethylene oxide polymers and polyethylene glycol in line 8. These are two different names for the same polymer. There is also a broad recitation of "natural gums" in line 10 and a more specific recitation of "gum Arabic" in line 7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the

claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim for the use of the administration form according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. As Applicants have elected restriction group I, drawn to products, the interpretation of this claim as a composition will be used for the purposes of applying art below.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

7. Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 – 5, 7 – 11, 13 – 15, 21, 22, 24 – 26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kigasawa et al. (US 4,572,832).

Kigasawa et al. discloses soft buccal compositions which comprise a medicament to be absorbed through the oral cavity, a water-soluble protein, a polyhydric alcohol and a fatty acid ester and/or a carboxyvinyl polymer (col 1, ln 36 – 49). Forms include sheets, bands and disks (col 6, ln 21 – 26). In example 8 (col 12, ln 43 – 60), a soft buccal comprising the active ingredient pindolol is prepared using the film forming polymer gelatin (gelatine), pH 6.5 phosphate buffer and the excipients propylene glycol, medium-chain fatty acid triglycerides, sucrose fatty acid ester, glycerin, mannitol and corn starch. The total weight of the excipients is about 70% of the total weight. After sonication to create a dispersion, the gelatin was added and the resulting mixture kneaded and cut into plate-shaped (a film-shaped) dosage form. This dosage form took between 16 minutes and 17 minutes, 15 seconds to disintegrate.

In example 8(a) (col 12, ln 24 – 42), gelatin was dissolved in water to which a pindolol dispersion was added, which was cut into pieces and dried to a plate like shape which was 17 mm long, 9 mm wide and 2 mm thick. This plate-shaped form took between 10 minutes, 30 seconds and 12 minutes, 40 seconds to disintegrate.

Therefore, Kigasawa et al. teaches a film-shaped, dried dosage forms comprising and active ingredient and at least one matrix-forming polymer whose pH value adapted to the physiological pH value of the mucosa to which the administration form is to be applied.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1 – 11, 13 – 15 and 20 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. (US 4,572,832).

Kigasawa et al. discloses soft buccal compositions which comprise a medicament to be absorbed through the oral cavity, a water-soluble protein, a polyhydric alcohol and a fatty acid ester and/or a carboxyvinyl polymer (col 1, ln 36 – 49). Forms include sheets, bands and disks (col 6, ln 21 – 26). In example 8 (col 12, ln 43 – 60), a soft buccal comprising the active ingredient pindolol is prepared using the film forming polymer gelatin (gelatine), pH 6.5 phosphate buffer and the excipients propylene glycol, medium-chain fatty acid triglycerides, sucrose fatty acid ester glycerin, mannitol and corn starch. The total weight of the excipients is about 70% of the total weight. After sonication to create a dispersion, the gelatin was added and the resulting mixture kneaded and cut into plate-shaped (a film-shaped) dosage form. This dosage form took between 16 minutes and 17 minutes, 15 seconds to disintegrate.

In example 8(a) (col 12, ln 24 – 42), gelatin was dissolved in water to which a pindolol dispersion was added, which was cut into pieces and dried to a plate like shape which was 17 mm long, 9 mm wide and 2 mm thick. This plate-shaped form took between 10 minutes, 30 seconds and 12 minutes, 40 seconds to disintegrate.

Therefore, Kigasawa et al. teaches a film-shaped, dried dosage forms comprising and active ingredient and at least one matrix-forming polymer whose pH value adapted to the physiological pH value of the mucosa to which the administration form is to be applied.

Kigasawa et al. does not explicitly prepare administration forms which contain aroma substances or cellulose derivatives. Kigasawa et al. also does not explicitly disclose an administration form which disintegrates in less than 10 minutes.

Kigaswa et al. discloses that additives can be added in addition to the required ingredients, including flavorings (aroma substances) such as menthol, lemon oil and citrus flavor as well as other excipients, disintegrating adjusting agents, emulsifiers, dispersants, binders and thickeners (col 5, ln 56 – col 6, ln 6). For the required polyhydric alcohol component can be ingredients such as ethylene glycol, propylene glycol, polyethylene glycol (col 4, ln 9 – 10). Also included in the category of polyhydric alcohols are cellulose and cellulose derivatives such as methyl cellulose, ethyl cellulose, hydroxymethyl cellulose, hydroxyethylcellulose and carboxymethyl cellulose (col 4, ln 18 – 28).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a dosage form with an aroma ingredient, taught by Kigaswa

et al. as an ingredient to impart a flavor/aroma to the medicament and to use a cellulose derivative such as ethyl cellulose for the required polyhydric alcohol component of the film administration.

The amount of an aroma ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. The aroma/flavor chosen and the strength of the aroma/flavor desired or required in the composition such as to mask the taste of a bitter active ingredient would determine the amount of the ingredient present in the composition.

In the test example 2 (beginning at col 16, ln 14), results on the bioavailability and pharmacokinetic data for sublingually administered films and oral administered dosage forms were compared. In these tests, the parameters for the soft buccal formulations were improved in comparison to oral administration. Steps had to be taken to prevent the test animals from swallowing the buccal administration forms (e.g., col 16, ln 23 – 25). A shorter the disintegration time in the mouth would make it less likely that the remaining portion of the administration form would be swallowed. Therefore, one of ordinary skill in the art would adjust the composition of the tablet in order to provide a fast disintegration of the dosage form to minimize the possibility for swallowing the dosage form and losing the benefits of the buccal administration form.

14. Claims 1 – 15 and 20 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al as applied to claims 1 – 11, 13 – 15 and 20 – 29 above, and further in view of Rault et al. (US 5,900,247).

As discussed in greater detail above, Kigasawa et al. discloses soft buccal administration forms of active ingredients that can be formulated as disks or wafers.

Kigasawa et al. does not disclose a multilayer dosage form.

Rault et al. discloses a bioadhesive pharmaceutical composition to locally release active ingredients through various mucosal membranes (col 1, ln 7 – 15). The bioadhesive composition comprises a vinyl acetate/polyvinylpyrrolidinone copolymer, at least one active ingredient, optionally a cellulose or cellulose derivative such as ethyl cellulose or hydroxypropylmethyl cellulose and excipients such as plasticizers flavoring agents or sweeteners. After spreading of the bioadhesive mixture onto a biodegradable or non-biodegradable protective film or substrate, the assembly is dried (col 2, ln 54 - 62). The protective film is chosen for its adhesive or bioadhesive properties and is peelable (col 2, ln 63 – 65). This process results in the production of a multilayered administration form. In example 4, a composition is prepared which contains approximately 3% by dry weight of flavoring agents.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a buccal administration form as taught by Kigasawa et al. and to place this material on a protective film, as taught by Rault et al., resulting in a multilayered administration form. Rault et al. also provides additional guidance to one of

ordinary skill in the art as to the amount of flavoring ingredients, which can include aroma substances, that can be added to such compositions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW